DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Kansas City District
Southwest Region
11630 W. 80th Street
Lenexa, Kansas 66214
Telephone: (913) 752-2100

January 14, 2004

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**
Ref. KAN 2005-05

G. Allen Andreas, Chairman and Chief Executive
Archer Daniels Midland Company (ADM)
4666 Faries Parkway
P.O. Box 1470
Decatur, Illinois 62526

Dear Mr. Andreas:

Representatives of the U.S. Food and Drug Administration conducted an inspection on July 27, 2004 – August 6, 2004, inclusive, of your medicated feed mill operation located at 1877 NE 58th Avenue, Des Moines, Iowa. During this inspection significant deviations from Current Good Manufacturing Practice (cGMP) Regulations for Medicated Feeds, Title 21 Code of Federal Regulations, Part 225 (21 CFR 225) and from Current Good Manufacturing Practice (cGMP) Regulations for Type A Medicated Articles (21 CFR 226). Such deviations cause the medicated feeds manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act). The deviations found include:

1. Your firm failed to assure that the equipment used in the manufacture of Type A Medicated Articles is operated in a manner that ensures the integrity of the finished product. [21 CFR 226.40(c)]. Your validation protocol does not adequately address a number of factors, such as sampling plan and its rationale, time required to add ingredients while the mixer is running but not timed, order in which bulk, liquid and hand-add ingredients are added to the mixer, addition of overages from past batches, rpm's of the mixer, mixer fill and bulk densities of ingredients, among others or, alternatively, include other factors that would assure that the equipment is operated in a manner that ensures the integrity of the finished product. We acknowledge your response though we recommend you review all your validation activities for distributed Type A Medicated Articles.

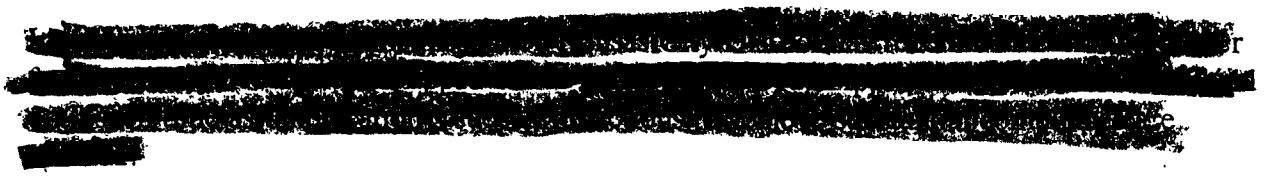
2. Your firm failed to adequately store incoming bulk drug components in a manner that assures the maintenance of their identity, strength, quality and purity. [21 CFR 225.42(b); 21 CFR 226.42(a)]. You store products that are labeled (on the product label of some products and on the Certificate of Analysis of other products) to be stored

in a "cool, dry place" in ambient temperatures in your warehouse. Your response indicates that the temperature at which some components are stored can be up to 80 degrees. Storing components at this temperature is not consistent with the labeling that states that products are to be stored in a "cool, dry place." The current USP, for example, defines cool as "[a]ny temperature between 8° C and 15° C" (46° and 59° F) and defines dry place as "a place that does not exceed 40% average relative humidity at *Controlled Room Temperature* or equivalent water vapor pressure at other temperatures."

In addition, in your [redacted] you stated that you would provide a designated finished goods quarantine area. You indicate that your facility uses computer inventory controls that make the entire warehouse a potential quarantine area for finished products. This may be acceptable if you can show that the system in place is appropriate to prevent any unapproved release of product. We have reviewed your firm's written response dated December 17, 2004 and find the procedures proposed in your addendum will be adequate if copiously followed by the operational personnel. This procedure will be evaluated during the next inspection at your facility.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of medicated and non-medicated feeds you are responsible for assuring that your overall operation and the products you manufacture are in compliance with the law. At the conclusion of the inspection Form FDA 483, Inspectional Observations, was issued to Monica K. Morse, Location Manager and discussed with her and Mr. Ralph P. Staiert, Quality Assurance Manager. This form is a comprehensive listing of deviations observed by the Investigators during the inspection. A copy of this form is enclosed for your information.

You should take prompt action to correct the noted violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License, under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2). Based on the results of the inspection, evaluated together with the evidence before FDA when the Medicated Feed Mill License was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies, as provided in Section 512 of the Act.



We have reviewed your response dated August 17, 2004 and it was considered during the preparation of this correspondence.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what additional steps you are taking to correct the problems. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent Ralph J. Gray, Compliance Officer, at the above address.

Sincerely,

John W. Thorsky
Acting District Director
Kansas City District Office

Enclosure

cc: Mr. Steve Dale, Vice President Operations
Mr. Randy Sample, Director Regulatory Affairs
ADM Animal Health and Nutrition
1000 N. 30th Street
Quincy, IL 62301

Ms. Monica K. Morse, Location Manager
ADM Animal Health and Nutrition
1877 NE 58th Avenue
Des Moines, IA 50313-1627